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10/516,868	12/03/2004	Dorothy French	P1959R1	1564

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EXAMINER
HIRIYANNA, KELAGINAMANE T

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 01/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/516,868	FRENCH ET AL.	
	Examiner	Art Unit	
	Kelaginamane T. Hiriyanna	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims **1-11** are pending and presently under examination.

Specification

Priority date for this invention applied under 35 USC §119(e) for the US provisional application serial number 60/387,264 filed on 06/07/2002 has been granted.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1-11 rejected under 35 U.S.C. 101 because claim is drawn to non-statutory subject matter. Claims drawn to transgenic animals carrying in their genome or at least some of their cells a recombinant genetic material, which encompasses humans. It is PTO policy not to allow claims to humans (1077 O.G. 24 April 1987). The insertion of non-human before transgenic animal, would overcome this rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

"The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the broadly claimed invention.

Claims 1-8 directed to transgenic mammals expressing FGF19 polypeptide, claim 9 directed to an isolated cell from said mammals and claim 10-11 directed to a method of

screening a biologically active agent that modulate a phenomenon associated with hepatocellular carcinoma employing said transgenic mammal or a cell of the same in culture.

The scope of the instant claims encompasses any and all non-human mammals that are transgenic for FGF 19 gene (see USC35 §101 rejection above for excluding humans in the generic claim) The claim in its breadth as read on the art includes monotremes to marsupials to elephants and whales etc., to name a few. The specification in the as filed application however, does not provide support for the breadth of the claim or to even a substantial part of it.

The specification only provides guidance and/or evidences regarding generation of a transgenic mouse with FGF19 cDNA driven by MLC promoter and its characterization (Example 8, p.91-95) and a method of drug screening (p.96, 3rd paragraph bridging p.97-98). The results of histopathological analyses, measurement of serum FGF19 protein, in situ hybridization analysis for FGFR4, the receptor for FGF19, immunohistochemical and morphometric analyses etc., presented in the as filed application suggest a role for FGF19 in hepatocarcinogenesis and hepatocellular proliferation and further indicate that tumors arise from pericentral hepatocytes following increased proliferation and dysplasia"(p.94, 2nd paragraph). Hepatocellular carcinomas in said transgenic mice were predominantly the solid type. However, no histological changes were observed in skeletal muscle. Application further contemplates drug design and screening methods employing said transgenic mouse and the cells derived thereof. However, no description or evidences of enabling the genus FGF19 transgenic mammals or even a substantial part of it is provided in the as filed application.

The state of the art at the time of filing teaches that FGF-19 is one of the several described members of fibroblast growth factors family (FGFs). FGFs are mitogenic cytokines and have been shown to have diverse activities on cells of meosdermal and ectodermal origin including for example, epithelial cell proliferation, differentiation and cell migrations and pattern formation during development, angiogenic and neurotrophic effects etc (Xie et al., 1999, Cytokine 11:729-735, p.1, 1st para). FGF 19 is unusual among FGF family members in that it is not mitogenic and appears to interact only with FGFR-4 receptor. FGF19 is expressed several tissues including cartilage, skin, retina, gall bladder etc., and is overexpressed in a colon adenocarcinoma cell line and in humans FGF-19 gene maps to chromosome 11 q13.1, a region associated with several human diseases.

Given the art described divergent expressions, interactions and cellular functions and association with multiple diseases, of the various members of the FGF family of proteins summarized above one of ordinary skill in the art would not be able to predict from the observations on phenotypic properties in a FGF19 transgenic mouse, that the other claimed transgenic mammals, would possess the same or similar phenotypes. Since the disclosure fails to describe the common attributes or characteristics that identify representative number of members of the said genus non-human transgenic mammals and/or methods and compounds for intended screening, one skilled in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. The claimed invention as a whole thus not adequately described in the specification and which is not conventional in the art as of applicants' effective filing date. Claiming all divergent species that achieve a result as contemplated by the application without defining the means and/or uses will do so not in compliance with the written description requirement. Rather, it is an attempt to preempt the future before it has arrived. "The written description requirement has several policy objectives. The essential goal' of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed." In re Barker, 559 F.2d 588, 592 n.4, 194 USPQ 470, 473 n.4 (CCPA 1977). Another objective is to put the public in possession of what the applicant claims as the invention. See Regents of the University of California v. Eli Lilly, 119 F.3d 1559, 1566, 43USPQ2d 1398, 1404 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089 (1998)."

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail such that the Artisan can reasonably conclude that the inventor(s) had possession of the claimed invention. Such possession may be demonstrated by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and/or formulae that fully set forth the claimed invention. Possession may be shown by an actual reduction to practice, showing that the invention as claimed is "ready for patenting", or by describing distinguishing identifying characteristics sufficient to show that applicant was in possession of the claimed invention (January 5, 2001 Fed.Reg., Vo.66, No. 4, pp. 1099-11).

At the best the instant specification discloses a transgenic mouse but fail to describe all mammals encompassed by the scope of invention as claimed.

Claims 1-11 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for (1) A transgenic mouse whose genome comprises: an integrated a nucleic acid construct comprising a promoter operably linked to ncucleic acid coding for FGF 19 polypeptide and wherein said mouse acquires hepatocellular carcinoma, proliferation of pericentral hepatocytes and exhibits elevated level of alpha-fetoprotein and (2) for a isolated cell from said transgenic mouse and a method of screening for biologically active agents that can affect FGF-19 associated hepatocellular carcinoma using said mouse or said cell, it does not reasonably provide enablement for the full scope, which embraces all transgenic mammals. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims as explained below.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (1) The breadth of the claims; (2) The nature of the invention; (3) The state of the prior art; (4) The level of one of ordinary skill; (5) The level of predictability in the art; (6) The amount of direction provided by the inventor; (7) The existence of working examples; and (8) The quantity of experimentation needed to make or use the invention based of the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). All of the wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below as to show that one of the ordinary skill in the art have to go through ‘’undue experimentation” in order to practice the invention.

Nature of the invention and the breadth of the claims: The claims are directed to a transgenic mammal comprising a exogenous nucleic acid coding for a generic nucleic acid encoding FGF 19 polypeptide and use of said transgenic mammal as tool for screening generic candidate therapeutic compounds for effectiveness in treating a disease. Applicants broadly claim generic biologically active agents encompassing an enormous number of unspecified

material(s) and/or methods and steps of screening for effectiveness on hepatocellular carcinoma. The claimed invention as pending embraces all transgenic mammals encompassing animals from monotremes to marsupials to elephants to man. Applicants' attention is drawn to In re Shokal, 242 F.2d 771, 113 USPQ 283 (CCPA 1957). The test is whether the species completed by applicant prior to the reference date or the date of the activity provided an adequate basis for inferring that the invention has generic applicability. Thus, the application does not reasonably provide enablement for the breadth and scope of the claimed of inventions.

The level of one of ordinary skill in the Art at the Time of Invention: The level of one of ordinary skill in the art at the time of filing of the instant application is high requiring an advanced degree or training in the relevant field. The status of the art at the time of filing was such that said skilled in the art would not have been able to make or use the invention for its fully claimed scope without undue experimentation.

***Guidance of the Specification and the Existence of Working Examples*:** The application does not reasonably provide enablement for the full scope of claims encompassing the genus transgenic mammals comprising FGF 19 transgene. The number and variety of working examples and embodiments and the information on the nature of the inventive product provided in the specifications in the instant application fail to enable the claims in its breadth even when read broadly in the light of the status of the art at the time of filing. The specification, as indicated earlier, does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope of the claims in the instant application. From the evidences and analysis presented above and in the light of the state of the art at the time of filing of instant application it is clear that the disclosures on a FGF 19 transgenic mouse with a conventional transgene is not enabling to represent all the FGF 19 transgenic mammals. Even after knowing certain uses of the FGF 19 transgenic mouse as a model for hepatocellular carcinoma, from the instant specification, it still requires undue experimentation for one skilled in the art to ascertain or predict the properties and phenotypes of the generically claimed inventions *a priori*.

***State of the Art, the Predictability of the Art and the Amount of Experimentation Necessary*:** FGF-19 is one of the many fibroblast growth factors (FGFs) that have been isolated and characterized. FGFs are mitogenic cytokines and have been shown to have diverse activities

on cells of meosdermal and ectodermal origin including for example, epithelial cell proliferation, differentiation and cell migrations and pattern formation during development, angiogenic and neurotrophic effects etc (Xie et al., 1999, Cytokine 11:729-735, p.1, 1st para). FGF 19 is unusual in that it is not mitogenic and appears to interact only with FGFR-4.

A transgenic mouse expressing a FGF19 transgene driven by MLC promoter, with a heptocellular carcinoma has been described. However, specification read in the light of Art do not do not enable the invention as claimed for the broad claims that embraces any and all non-human mammals expressing FGF19 transgene.

Note that the mere capability to perform gene transfer in a mouse is not enabling because a desired phenotype wherein the FGF 19 is overexpressed in animals cannot be predictably achieved by simply introducing targeting constructs of the types recited in the claims. Bockamp et al. Physiol. Genomics 11:115-132, 2001, state that "In experimental settings, use of conventional transgenic technology control over the onset of transgene expression will strictly depend on positional integration effects and on the nature of the chosen regulatory elements. However, constitutive expression of a transgene is often too inflexible to meet the needs of a specific experimental question. For example, too early or too widespread expression of the transgene may lead to phenotypic or physiological aberrations producing secondary pleiotropic responses as a result of the introduced genetic alteration. Distinguishing effects of the resulting phenotype might turn out to be extremely difficult, as cell autonomous versus cell non-autonomous effects are not clearly divisible and compensatory systemic changes are often concealed. In addition, for many experimental questions it might be necessary to analyze the function of a transgene within a specific developmental window or in a particular cell lineage. Unfortunately, adequate temporal or tissue-restricted promoters may not always be available. For these reasons, the perfect conditional transgenic mouse should, in principle, include the following criteria. First, induced over expression of the transgene should be tightly controlled such that no leaky background expression precludes the accurate analysis. Second, the inducing compound should be nontoxic and highly specific for the target gene. Third, induction kinetics should be fast and expression levels sufficiently high to produce a rapid and detectable effect. Fourth, the induced switch should be reversible so that defined developmental periods or critical stages in disease can be appropriately monitored".

Unpredictability of phenotypes in conventional transgene technique arises due to transgene random integration into the host genome and subsequent aberrations namely poor expression, temporally and/or spatially aberrant expression, position effects etc., (Bishop Reproductive Nutrition and Development 36: 607-616, 1996; p.614 1st col. 3rd pg. & 2nd col. 1st¶). Further unpredictability arises owing to the functional and physiological effects of the expressed transgene (foreign gene), interference of the redundant native genes, induction of compensatory processes, gene silencing effects as well as due to the influence of genetic background and the phenomenon of imprinting (reviewed in Rulicke and Hubischer, Experimental Physiology 85: 589-601, 2000; p.595 1st col. 1st ¶). Holschneider et al. Int J. Devl. Neuroscience 18:615-618, 2001, discuss various factors that contribute to the resulting phenotype of transgenic mice, including compensatory systems which may be activated to mask the resulting phenotype, these compensatory changes may be due to the differential expression of another gene, which may be regulated by the downstream products for the formation of desired muscle fibers. "The use of conditional and inducible transgenic systems can permit the study of a phenotype containing or lacking the transgene product at any given developmental stage of the same individual. This could enable experimental approaches that can either focus on specific time points or in specific tissues during development, on effects of the duration of transgene expression and on the reversibility of induced phenotypes" (Rulicke & Hubischer, Experimental Physiology 85: 589-601, 2000; se p. 597, 1st col., 4th ¶).

Amount of experimentation necessary: These claims are not enabled because one of skill in the art would not be able to produce the whole genus of transgenic mammals, as instantly claimed, exhibiting the required phenotypes, and further, one would not be able to use these mammals, since the applicants are not in the possession of claimed genus. One of skilled in the art would not be able to rely upon the state of the art in order to produce all mammals with the claimed phenotypes, because of the unpredictability associate with expressed phenotypes I variety of transgenic mammal. Accordingly, in view of the lack of teachings or guidance provided by the specification with regard to an enabled use for genus mammals comprising a exogenous FGF19 transgene, the lack of teachings or guidance provided by the specification to overcome the art-recognized unpredictability with regard to what the phenotypes and properties and uses are of such transgenic nonhuman mammals are as well as due to lack of representative

number of specific working examples for the broadly claimed methods of screening and for the specific reasons cited above, it would have required undue experimentation for one of skill in the art to make and use the full scope of the claimed invention. At the best the specification as filed is found only enabled for FGF19 transgenic mouse and a method of use.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1-9 are rejected under 102(e) as being anticipated by Stewart et al., (Pub No. US 2002/00442367 A1, April 11, 2002: of US patent App. No. 09767609, filing date Jan 22, 2001).

Stewart et al., teach (p.47 co.1, paragraphs 4-6 bridging col.2 and in claims 80, p.55, co.2, line 18) a transgenic mouse comprising a human FGF-19. The transgenic mice of Stewart et al., address all the limitations of the claims 1-3 of the instant application including a transgenic FGF19 mouse with a stably integrated myosin light chain promoter operably linked to nucleotide sequence coding for FGF19 and expressing FGF19 in skeletal muscles.

Absent evidence to the contrary, Stewart et al., anticipates all the rejected claims.

Claims 1-11 are rejected under 102(a) as being anticipated by Nicholes et al., (American Journal of Pathology 2002, 160: 2295-2307).

Nicholes et al., teach (p.1 col.1) a transgenic mice comprising FGF-19 transgene and driven by myosin light chain (MLC) promoter has been generated and characterized as a mouse model of hepatocellular carcinomas. The transgenic mouse of Nicholes et al., addresses all the limitations of the claims 1-9 of the instant application.

Absent evidence to the contrary, Nicholes et al., anticipates all the rejected claims.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Absent evidence to the contrary, Stewart et al., and Nicholes et al., anticipates all the rejected claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1-11 are rejected under 35 USC 103 (a) as being unpatentable over Nicholes et al, (American Journal of Pathology 2002, 160:2295-2307) in view of Bostein et al (USPTO Pub.No. US2002/00112961). The rejection of claim 9-11 as being anticipated by Nicholes et al., is applied here as indicated above. Nicholes et al., teach (p.1 col.1) a transgenic mice comprising FGF-19 transgene and driven by myosin light chain (MLC) promoter has been generated and characterized as a mouse model of hepatocellular carcinomas. The transgenic mouse of Nicholes et al., addresses all the limitations of the claims 1-9 of the instant application.

However, Nicholes et al does not teach the limitation of a method of screening for biologically active agents that modulate a phenomenon associated with hepatocellular carcinoma.

At the time the invention was made, Bostein et al., teaches the cells with over expressing FGF-19 protein. Bostein further teaches "that these cells are useful targets of diagnosis and or treatment (including prevention) of certain cancers, and may act as predictors of the prognosis of tumor treatment. Further more, the compounds and compositions including antagonists and methods of the invention are expected to have therapeutic effect upon conditions characterized by FGF-19 modulation"(se abstract).

It would have been obvious for one of ordinary skill in the art to incorporate the methods of screening biologically active agents for hepatocellular carcinoma using the cells of FGF-19 over expressing mice, in vitro or in vivo. One of ordinary skill in the art would have been motivated to employ drug screening methods for hepatocellular carcinoma in cells of FGF-19 transgenic mice as it would help in identifying therapeutic compounds or diagnostic markers for diagnosis and treatment of hepatocellular carcinoma, and because Nicholes et al., teach that FGF1-19 overexpressing mice are good mouse model for studies on said disease and Bostein et al., teaches the compounds, compositions including antagonists and the methods of FGF-19 modulation. One of ordinary skill I the art would have reasonable expectation of success in making and using of biologically active compounds to treat a hepatocellular carcinoma because of the results shown both in Nicholes and Bostein's references. Thus, the claimed invention was *prima facie* obvious.

Conclusion:

No claim allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Kelaginamane Hiriyanna* whose telephone number is **(571) 272-3307**. The examiner can normally be reached Monday through Friday from 9 AM-5PM. Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst *Victor Barlow*, whose telephone number is **(571) 272-0506.** If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Dave Nguyen*, may be reached at **(571) 272-0731.** The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). When calling please have your application serial number or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. For all other customer support, please call the USPTO call center (UCC) at (800) 786-9199.

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